FROM: Rita Panar
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July 19, 1999

TO: Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20857-0003

RE: Docket No. 98N-1265

I send this letter as a resident of the State of Delaware and as a consumer of healthcare services to register my concern and disapproval of the Memorandum of Understanding as published by the FDA on January 21, 1999.

In its present form, the MOU, as well as the Compounding Section 503A of the Modernization Act, severely restricts the rights of the physicians and patients to obtain healthcare products from the provider of their choice. It also infringes on the rights of compounding pharmacists to serve the public's medical needs. As a healthcare consumer, there should be no restrictions to the delivery of a compounded medication prescribed for me, regardless of where I may live or may travel. The MOU must be amended!

In particular, I wish to protect my access to the natural micronized hormones componded by Womens' International Pharmacy which have been prescribed for me since 1995 by my gynecologist, Dr. J. Tildon-Burton, to alleviate the symptoms of menopause.

Prior to beginning this hormone replacement therapy I was suffering from daytime hot flashes and night sweats which prevented me from getting a restful night's sleep. These symptoms were accompanied by anxiety and apprehension and, most debilitatingly, by panic attacks which would strike at anytime with no obvious cause. These combined to cause general depression from the untreated menopause.

I had begun to consider asking my primary care physician to consider putting me on an antianxiety - antidepressant medication such as Prozac or Zoloft to see if that might restore my sense of emotional balance and enable me to resume my normal life. While I was hesitating - because my body has a tendency to over-react to such medication - I learned that my anxiety and panic attacks could also be symptoms of menopause. So I changed from a gynecologist who did not believe in hormone replacement therapy to Dr. Tildon-Burton. In light of my history of stress and anxieties, Dr. Tildon-Burton considered it inadvisable to risk more anxiety or depression as a side-effect of the synthetic progestins normally used in combination with the conjugated estrogens in commercial and popular hormone replacement therapies. Therefore she suggested the compounded natural micronized hormones which do not normally have that side-effect.

Because of my history of stress and anxieties with menopause, because estrogen therapy is considered to reduce the likelihood of osteoporosis and because the micronized estradiol in the micronized compound I am taking is considered to be, not only noncarcenogenic, but even anticarcenogenic - for these reasons, I would like to continue to be able to obtain the natural micronized hormones from Womens' International Pharmacy and to have my company's managed care plan continue to cover it.

The FDA is an agency of the U.S. Government that purports to be the "watchdog" for consumer safety. However, with this MOU you are about to "protect" me out of the safest hormone replacement therapy now available to me!! As a governmental agency, the FDA also has a responsibility to be accountable to the people. Once again, the MOU must be amended!

Thank you for the courtesy of your attention and, in advance, for amending the MOU, Docket No. 98N-1265.

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